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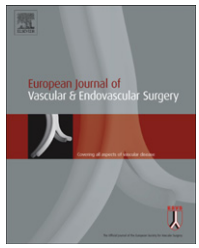

Selected Abstracts from the October Issue of the Journal of Vascular Surgery☆

Editors: Anton N. Sidawy and Bruce A. Perler

Results of the randomized, placebo-controlled clopidogrel and acetylsalicylic acid in bypass surgery for peripheral arterial disease (CASPAR) trial

Jill J.F. Belch, John Dormandy

Objective: Dual antiplatelet therapy with clopidogrel plus acetylsalicylic acid (ASA) is superior to ASA alone in patients with acute coronary syndromes and in those undergoing percutaneous coronary intervention. We sought to determine whether clopidogrel plus ASA conferred benefit on limb outcomes over ASA alone in patients undergoing below-knee bypass grafting.
Methods: Patients undergoing unilateral, below-knee bypass graft for atherosclerotic peripheral arterial disease (PAD) were enrolled 2 to 4 days after surgery and were randomly assigned to clopidogrel 75 mg/day plus ASA 75 to 100 mg/day or placebo plus ASA 75 to 100 mg/day for 6 to 24 months. The primary efficacy endpoint was a composite of index-graft occlusion or revascularization, above-ankle amputation of the affected limb, or death. The primary safety endpoint was severe bleeding (Global Utilization of Streptokinase and Tissue plasminogen activator for Occluded coronary arteries [GUSTO] classification).
Results: In the overall population, the primary endpoint occurred in 149 of 425 patients in the clopidogrel group vs 151 of 426 patients in the placebo (plus ASA) group (hazard ratio [HR], 0.98; 95% confidence interval [CI], 0.78-1.23). In a prespecified subgroup analysis, the primary endpoint was significantly reduced by clopidogrel in prosthetic graft patients (HR, 0.65; 95% CI, 0.45-0.95; P = .025) but not in venous graft patients (HR, 1.25; 95% CI, 0.94-1.67, not significant [NS]). A significant statistical interaction between treatment effect and graft type was observed ($P_{interaction}$ = .008). Although total bleeds were more frequent with clopidogrel, there was no significant difference between the rates of severe bleeding in the clopidogrel and placebo (plus ASA) groups (2.1% vs 1.2%).
Conclusion: The combination of clopidogrel plus ASA did not improve limb or systemic outcomes in the overall population of PAD patients requiring below-knee bypass grafting. Subgroup analysis suggests that clopidogrel plus ASA confers benefit in patients receiving prosthetic grafts without significantly increasing major bleeding risk.

Quality of life in patients with no-option critical limb ischemia underlines the need for new effective treatment

Ralf W. Sprengers, Martin Teraa, Frans L. Moll, G. Ardine de Wit, Yolanda van der Graaf, Marianne C. Verhaar

Objective: To provide a solid baseline reference for quality of life (QoL) in patients with no-option critical limb ischemia (CLI). CLI is associated with surgery, endovascular interventions, hospitalization, and a poor prognosis. An increasing number of clinical trials are, therefore, investigating new treatment strategies (eg, therapeutic neovascularization) in patients with CLI. QoL serves as an important secondary endpoint in many of these trials, but solid reference QoL data for patients with no-option CLI are lacking.
Methods: The Medical Outcomes Study Short Form 36 (SF-36) and the EuroQol-5D (EQ-5D) questionnaires were used to obtain baseline QoL scores from 47 patients with no-option CLI participating in a therapeutic neovascularization trial. To allow for easy comparability, a norm-based scoring (NBS) method was used to report the results of the SF-36. Scores of patients with CLI were furthermore compared with scores of patients with milder forms of peripheral arterial disease (PAD) and with patients with cardiovascular risk factors only. Determinants of QoL in patients with PAD were identified using multiple linear regression methods.
Results: Patients with no-option CLI reported QoL scores below the general population mean on every health dimension of the SF-36. Physical functioning, role physical functioning, and bodily pain were affected most intensively. These poor physical QoL scores were further underlined when compared with other patients with milder forms of PAD or patients with cardiovascular risk factors only. Patients with CLI scored poorly on the pain/discomfort and the usual activities domain of the EQ-5D. Diabetes, female gender, body mass index, and the ankle-brachial index at rest were significant determinants of the QoL in PAD on multivariate analysis.
Conclusion: The QoL data of patients with no-option CLI using NBS methods for the SF-36 provide a baseline reference for ongoing clinical trials on new treatment strategies. Our data stress the need for new revascularization therapies in patients with no-option CLI.

Open and endovascular repair of type B aortic dissection in the Nationwide Inpatient Sample

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Background: The use of stent grafts and mortality of stent graft repair of type B thoracic aortic dissection (T_BAD) is not well defined. We sought to determine national estimates for the use and mortality of thoracic endovascular aortic repair (TEVAR) for T_BAD in the United States.
Methods: Records of the Nationwide Inpatient Sample (NIS) database between 2005 and 2007 were examined. *International Classification of Diseases, 9th edition* (ICD-9) diagnosis codes were used to select patients who underwent open or TEVAR with a stent graft for a diagnosis of thoracic aortic dissection or thoracoabdominal aortic dissection. We excluded patients with a diagnosis code for aortic aneurysm and those with procedure codes for cardioplegia or for operations on heart vessels or valves, which were considered type A dissections (T_AAD). The remaining patients were considered as T_BAD. We compared demographics and comorbidities, as well as adjusted complications and mortality rates, between patients undergoing TEVAR vs open repair.
Results: We identified an estimated 10,466 repairs for dissection of the thoracic or thoracoabdominal aorta (open, 8659; TEVAR, 1818). Of these, 464 had a diagnosis of aortic aneurysm, and 5002 patients were considered T_AAD. Of nonaneurysmal dissections, 5000 repairs were considered T_BAD (open, 3619; TEVAR, 1381). The endovascular patients were older and had

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greater comorbidities, although only cardiac disease, renal failure, hypertension, and peripheral vascular disease were statistically significant. In-hospital mortality was 19% for open repair vs 10.6% for TEVAR (odds ratio [OR], 2.24; 95% confidence interval [CI], 1.36-3.67; $P < .01$). In-hospital mortality was significantly higher with open repairs coded as emergent admissions (20.1% vs 13.1%; $P = .03$), but did not reach statistical significance for elective admissions (12.3% vs 4.8%; $P = .09$). Cardiac complications (12.4% vs 4.9%, $P < .01$), respiratory complications (7.7% vs 4.3%, $P = .02$), genitourinary complications (9.0% vs 2.5%, $P < .01$), hemorrhage (14.0% vs 2.8%, $P < .01$), and acute renal failure (32.1% vs 17.2%, $P < .01$) were more frequent in the open repair group. Median length of stay was greater in the open repair group (10.7 vs 8.3 days, $P < .01$).
Conclusion: For patients with a diagnosis of T_BAD who undergo repair, the endovascular approach is being used for older patients with greater comorbidities, yet has reduced morbidity and in-hospital mortality. The use of endovascular stent graft repair for type B thoracic aortic dissection merits further longitudinal analysis.

Endovascular repair of thoracic aortic traumatic transections is a safe method in patients with complicated injuries

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Purpose: Historically thoracic aortic rupture secondary to trauma was treated with cardiopulmonary bypass and open surgery. With the advent of endovascular grafting, physicians have the ability to reconstruct the thoracic aortic transection using a less invasive technique. In this study, we examine our experience with stent graft repair of thoracic transections secondary to trauma.
Methods: The medical records of patients treated at a level I trauma center from 2005 to 2008 were reviewed. Those patients who had an aortic transection treated with an endograft were identified and evaluated for in-hospital mortality and morbidity and concurrent injuries. Demographics, procedural details, and outcomes were analyzed.
Results: Over a 3-year period, 18 thoracic aortic transections secondary to trauma were identified in patients with a mean age of 43 (range, 16-80). Primary technical success was 100%. None of the patients required explant or open repair during this time period. In-hospital mortality was 2 of 18 (11%); all patients had multiple trauma including long bone fractures. The subclavian artery origin was covered by the stent graft in 9 of the 18 patients. The mean estimated blood loss per procedure was 222 cc. No patient in this series had postoperative paraplegia. Follow-up ranged from 1 to 50 months with an average of 13 months. There have been no late explantation or device failures identified.
Conclusion: Endovascular repair of traumatic thoracic aortic transections can be performed safely with a relatively low mortality and morbidity and should be the procedure of choice for patients presenting with traumatic thoracic aortic ruptures.

Restenosis after carotid endarterectomy in a multicenter regional registry

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Background: Level I evidence shows conventional carotid endarterectomy (CEA) with patch angioplasty results in lower rates of restenosis. However, whether this information has affected practice patterns and outcomes in real-world vascular surgery settings is unclear.
Methods: Within the Vascular Study Group of New England (VSGNE), we studied 2981 patients undergoing 2981 first-time CEAs between January 1, 2003, and June 31, 2008. Rates of restenosis (defined by duplex ultrasound imaging at the 1-year follow-up) were estimated using life-table analysis. Cox proportional hazards models were used to identify multivariable predictors of postoperative restenosis $\leq$1 year.
Results: Across 58 surgeons and 11 hospitals, we studied 2611 conventional CEAs (88% of all CEAs) and 370 eversion CEAs (12% of all CEAs). Median follow-up was 12.8 months (range, 1-35 months). The proportion of conventional CEAs performed with patching increased from 87% to 96% ($P < .001$) between 2003 and 2008, whereas eversion CEA declined from 18% to 5% ($P < .001$). Restenosis occurred in 303 patients (10%); by life-table analysis, the restenosis rate at 1 year was 6.2% (95% confidence interval [CI], 4.7%-6.8%). Restenoses were most commonly noncritical: 50%-79% restenosis in 7.9%, 80%-99% restenosis in 1.7%, and occlusion in 0.5%. Univariate analyses showed significant differences in 80% to 100% restenosis by procedure type (2% in conventional CEA, 6% in eversion CEA, $P < .002$), the year of procedure (3.2% in 2003, 0% in 2008; $P < .03$), and use of patching in conventional CEA (2.9% no patch, 1% with patch; $P < .008$). By multivariable analysis, absence of patching (hazard ratio [HR], 3.2; 95% CI, 1.5-7.0), contralateral internal carotid artery stenosis >80% (HR, 4.1; 95% CI, 1.4-11.5), and dialysis dependence (HR, 3.5; 95% CI, 1.2-9.8) were independently associated with a higher risk of an 80% to 100% restenosis. Of the 51 patients with 80% to 99% restenosis, 14 underwent reintervention $\leq$1 year, comprising 4 reoperations and 10 carotid artery stent procedures. Of the 15 patients with a carotid occlusion $\leq$1 year, transient ischemic attacks occurred in 2 and a disabling stroke in 1.
Conclusions: In our region, restenosis after CEA, especially clinically significant restenosis $\leq$1 year after surgery, decreased slightly over time. This improvement in outcome was associated with several factors, including an increase in patching after conventional CEA, a process of care that was studied and encouraged within our vascular study group. These results highlight the utility of regional quality-improvement efforts in improving outcomes in vascular surgery.

Outcomes of carotid stenting compared with endarterectomy are equivalent in asymptomatic patients and inferior in symptomatic patients

Jeannine K. Giacovelli, Natalia Egorova, Rajeev Dayal, Annetine Gelijns, James McKinsey, K. Craig Kent

Background: Despite the current Centers for Medicare and Medicaid Services coverage criteria for carotid artery stenting (CAS), consensus regarding its appropriateness in patients with carotid artery stenosis has not been reached. This is one of the first population-based studies to use a dedicated administrative convention for the endovascular procedure to address whether there is a cohort of patients in whom CAS is more beneficial than carotid endarterectomy (CEA).
Methods: We analyzed in-hospital mortality, postoperative stroke, and combined postoperative stoke/mortality in 47,752 CAS or CEA hospitalizations, matched by propensity score, in discharge data sets obtained from the states of New York and California for the years 2005 to 2007. Other outcomes included postoperative complications, length of stay, and volume-outcome relationships.
Results: For symptomatic patients undergoing CAS, rates were significantly higher for in-hospital mortality (3.7% vs 1.3%) and combined stroke/mortality (8.3% vs 4.6%) compared with CEA. For asymptomatic patients, there was no statistical difference between mortality (0.6% vs 0.4%), stroke (2.0% vs 1.8%), or combined stroke/mortality (2.4% vs 1.9%) across the endovascular and open procedures, respectively. Postoperative respiratory and urinary complications as well as cranial neuropathy were more common after CEA, whereas postoperative complications, including device malfunction and hypotension, were more frequent after CAS. We did not find a volume-outcome relationship for CEA, but one did exist for CAS.
Conclusions: In symptomatic patients with carotid artery stenosis, the most appropriate procedure appears to be CEA, whereas CAS appears to be a suitable minimally invasive approach for asymptomatic patients. On the basis of these results and data from recent multicenter randomized trials, the use of CAS in symptomatic patients should be approached with caution.

Accuracy of duplex sonography scans after renal artery stenting

Shawn H. Fleming, Ross P. Davis, Timothy E. Craven, Joel K. Deonanan, Christopher J. Godshall, Kimberley J. Hansen

Purpose: Reports of duplex sonography scan criteria for recurrent renal arterial (RA) stenosis after endoluminal stenting have suggested that criteria for native arteries may overestimate recurrent disease. This retrospective report examines the utility of renal duplex sonography (RDS) scans to define the presence of significant (ie, $\geq$60%) renovascular disease (RVD) after percutaneous angioplasty and endoluminal stenting (PTAS).
Methods: Demographic, duplex, and angiographic data were reviewed and compared. RDS was obtained. Peak systolic velocities (PSV) were obtained

after PTAS from multiple sites along the main RA from both anterior and flank approaches. Comparable images from digital subtraction angiography were independently examined for restenosis. Percent diameter stenosis was determined from the site of maximal stenosis compared with the normal RA distal to the stent. Sensitivity and specificity were estimated and 95% confidence intervals (CIs) were computed after adjusting for within patient ''clustering'' of observations applying native RA RDS criteria using angiography as the gold standard. Receiver operating characteristic (ROC) curves were used to estimate the optimal RDS values for recurrent stenosis.

Results: From October 2003 to June 2009, 49 patients had angiographic imaging after PTAS. There were 30 patients (18 women, 12 men; mean age, 71 $\pm$ 9 years) provided technically adequate paired angiographic and RDS assessment after PTAS for 66 RAs. Paired analysis was performed for 23 RAs after primary PTAS and 43 RAs after secondary treatment. The prevalence of significant restenosis was 35% (23 of 66 RAs). RAs with greater than 60% diameter restenosis had higher peak systolic velocity (PSV) compared to those without (2.48 $\pm$ 1.15 millisecond vs 1.44 $\pm$ 0.58 millisecond; $P < .001$). Compared to angiography, RA-PSV $\geq$1.8 millisecond with distal RA turbulence demonstrated a sensitivity of 73% (95% CI, 54%, 91%), specificity of 80% (95% CI, 67%, 93%), and an overall accuracy of 77% (95% CI, 67%, 88%) with a positive predictive value of 64% (95% CI, 46%, 82%). Optimal RDS value estimated by ROC curve resulted in RA-PSV of 2.5 millisecond which was associated with a sensitivity of 59% (95% CI, 36%, 82%), specificity of 95% (95% CI, 89%, 100%), an accuracy of 83% (95% CI, 74%, 92%), and a positive predictive value of 87% (95% CI, 68%, 100%).

Conclusion: Renal duplex sonography has utility to detect significant restenosis after PTAS. RDS criteria for significant native RA stenosis compare favorably with optimal RDS criteria for restenosis estimated by ROC curves.

Endovascular and open surgery for acute occlusion of the superior mesenteric artery

Tomas A. Block, Stefan Acosta, Martin Björck

Background: Acute thromboembolic occlusion of the superior mesenteric artery (SMA) is associated with high mortality. Recent advances in diagnostics and surgical techniques may affect outcome.

Methods: Through the Swedish Vascular Registry (Swedvasc), 121 open and 42 endovascular revascularizations of the SMA at 28 hospitals during 1999 to 2006 were identified. Patient medical records were retrieved, and survival was analyzed with multivariate Cox-regression analysis.

Results: The number of revascularizations of the SMA increased over time with 41 operations in 2006, compared to 10 in 1999. Endovascular approach increased sixfold by 2006 as compared to 1999. The endovascular group had thrombotic occlusion ($P < .001$) and history of abdominal angina ($P = .042$) more often, the open group had atrial fibrillation more frequently ($P = .031$). All the patients in the endovascular group, but only 34% after open surgery, underwent completion control of the vascular reconstruction ($P < .001$). Bowel resection ($P < .001$) and short bowel syndrome (SBS; $P = .009$) occurred more frequently in the open group. SBS (hazard ratio [HR], 2.6; 95% confidence interval [CI], 1.3-5.0) and age (HR, 1.03/year; 95% CI, 1.00-1.06) were independently associated with increased long-term mortality. Thirty-day and 1-year mortality rates were 42% vs 28% ($P = .03$) and 58% vs 39% ($P = .02$), for open and endovascular surgery, respectively. Long-term survival after endovascular treatment was better than after open surgery (log-rank, $P = .02$).

Conclusion: The results after endovascular and open surgical revascularization of acute SMA occlusion were favorable, in particular among the endovascularly treated patients. Group differences need to be confirmed in a randomized trial.